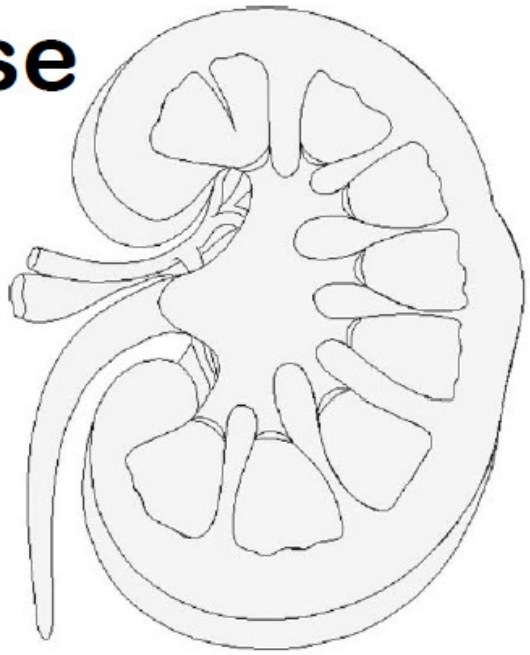
Guidelines for Vaccinating

Kidney Dialysis Patients and Patients with Chronic Kidney Disease



summarized from
Recommendations of the Advisory Committee on Immunization Practices (ACIP)

December 2012

This summary is not meant to apply to chronic kidney disease patients who are recently post-transplant. These patients are considered more significantly immunosuppressed than those who have only chronic kidney disease, with or without dialysis. The childhood and adult immunization schedules and a comprehensive listing of current ACIP recommendations can be found at http://www.cdc.gov/vaccines/

Prepared by:
Carolyn Chi, B.S.
Priti Patel, M.D., M.P.H.
Tamara Pilishvili, M.P.H.
Matt Moore, M.D.
Trudy Murphy, M.D.
Ray Strikas, M.D., M.P.H.

Guidelines for Vaccinating Dialysis Patients and Patients with Chronic Kidney Disease

summarized from
Recommendations of the Advisory Committee on Immunization Practices (ACIP)

December 2012

This summary is not meant to apply to chronic kidney disease patients who are recently post-transplant. These patients are considered more significantly immunosuppressed than those who have only chronic kidney disease, with or without dialysis.

Vaccination of Dialysis Patients and Patients with Chronic Kidney Disease (CKD)

Determination of chronic kidney disease is important to the vaccine provider because incidence or severity of some vaccine-preventable diseases is higher in persons with altered immunocompetence*; therefore, certain vaccines (e.g., inactivated influenza vaccine and pneumococcal vaccines) are recommended specifically for persons with immune compromise. In addition, vaccines might be less effective during a period of altered immunocompetence. Inactivated vaccines administered during a period of altered immunocompetence might need to be repeated. Because secondary antibody responses are less affected by immune compromise than primary antibody responses, immunization strategies should be formulated early in the course of progressive renal disease to maximize likelihood of vaccine-induced immunity. This approach is particularly important if transplantation and chronic immunosuppressive therapy are being considered.[1] Live vaccines might need to be deferred if severe immune compromise is present; persons with altered immunocompetence might be at increased risk for an adverse reaction after administration of live, attenuated vaccines because of uninhibited replication.[2] However, the majority of persons with CKD (regardless of CKD stage) have sufficient immune function to safely receive all live vaccines for which an inactivated vaccine is not an alternative.

* "Altered immunocompetence" will be used in this document synonymously with immunosuppression and immunocompromise.

List of Vaccines and their use for Dialysis or CKD Patients

Vaccine	Recommended for Dialysis or CKD Patients	Recommended for All Adults	May Use if Otherwise Indicated*	Contraindicated
Anthrax			X	
DTaP/Tdap/Td		X	X	
Hib			X	
Hepatitis A			X	
Hepatitis B	X (see p. 4)			
Human papillomavirus			X	
Influenza (TIV)		X (see p. 6)		
Influenza (LAIV)				X (see p. 6)
Japanese Encephalitis			X	
MMR		X	X	
Meningococcal			X	
Pneumococcal	X (see p. 7)			
Polio (IPV)			X	
Rabies			X	
Rotavirus			X	
Smallpox			X	
Typhoid			X	
Varicella		X	X	
Yellow Fever			X	
Zoster			X	

*No specific ACIP recommendation for this vaccine exists for dialysis patients or patients with chronic kidney disease.

NOTES

Hepatitis B Vaccine

"Hepatitis B vaccination is recommended for all susceptible chronic hemodialysis patients. . . Vaccination is recommended for pre-end-stage renal disease patients before they become dialysis dependent, and for peritoneal and home dialysis patients because they might require in-center hemodialysis.
“Patients with uremia who were vaccinated before they required dialysis have been shown to have higher seroprotection rates and antibody titers. The response to hepatitis B vaccination may also be better in children.” [1]

Dosage and Schedule
For patients undergoing hemodialysis and for other immunosuppressed patients, higher vaccine dosages or an increased number of doses are recommended. One formulation of hepatitis B vaccine designed for hemodialysis patients and other immunocompromised adults (age ≥20 years) patients contains an increased dosage and is administered in a 3 dose schedule (Recombivax HB, 40 µg/mL, Merck & Co., Inc, Whitehouse Station, New Jersey).[1] The other available formulation of hepatitis B vaccine is administered at a double standard dosage in a 4 dose schedule for hemodialysis patients and other immunocompromised adults (age ≥20 years) patients (two Engerix-B, 20ug [1.0 mL doses] administered in 1 or 2 injections, GlaxoSmithKline Biologicals, Rixensart, Belgium).[3]

"If an adult patient begins the vaccine series with a standard dose before beginning hemodialysis treatment, then moves to hemodialysis treatment before completing the series, complete the series using the higher dose recommended for hemodialysis patients. No specific recommendations have been made for higher doses for pediatric hemodialysis patients. If a lower than recommended vaccine dose is administered to either adults or children, the dose should be repeated."[3]

Immunogenicity and Duration of Immunity
Compared with immunocompetent adults, hemodialysis patients are less likely to have protective levels of antibody after vaccination with standard vaccine dosages; protective levels of antibody developed in 67%–86% (median: 64%) of adult hemodialysis patients who received 3–4 doses of either vaccine in various dosages and schedules. Higher seroprotection rates have been identified in patients with chronic renal failure, particularly those with mild or moderate renal failure, who were vaccinated before becoming dialysis dependent. [4]
"Limited data are available on the duration of immune memory after hepatitis B vaccination in . . . dialysis patients. No clinically important HBV infections have been documented among immunocompromised persons who maintain protective levels of anti-HBs. . . . However, among hemodialysis patients who respond to the vaccine, clinically significant HBV infection has been documented in persons who have not maintained anti-HBs concentrations of ≥10 mIU/mL."[5]

Serologic Testing
Testing after vaccination is recommended for hemodialysis patients to determine their response to the vaccine. Testing should be performed 1-2 months after administration of the last dose of the vaccine series by using a method that allows determination of a protective level of anti-HBs (e.g., ≥10 mIU/mL).

"Persons found to have anti-HBs levels of <10 mIU/mL after the primary vaccine series should be revaccinated with a second hepatitis B vaccination series. Administration of three or four doses on an appropriate schedule followed by anti-HBs testing 1-2 months after the third dose is usually more practical than serologic testing after one or more doses of vaccine."[4]

Persons who do not have a protective concentration of anti-HBs after revaccination should be tested for HBsAg. If the HBsAg test result is positive, the person should receive appropriate

management, and any household, sex, or needle-sharing contacts should be identified and vaccinated. Persons who test negative for HBsAg should be considered susceptible to HBV infection and should be counseled about precautions to prevent HBV infection and the need to obtain HBIG postexposure prophylaxis for any known or likely parenteral exposure to HBsAg positive blood. [4]

Booster Doses

"For hemodialysis patients, the need for booster doses should be assessed by annual testing for antibody to hepatitis B surface antigen (anti-HBs). A booster dose should be administered when anti-HBs levels decline to <10 mIU/mL."[4]

Influenza Vaccine

Inactivated Influenza Vaccine (TIV)

Routine annual influenza vaccination is recommended for all persons aged ≥6 months. To permit time for production of protective antibody levels, vaccination optimally should occur before onset of influenza activity in the community. Therefore, vaccination providers should offer vaccination as soon as vaccine is available. Vaccination should be offered throughout the influenza season (i.e., as long as influenza viruses are circulating in the community).[6]

"Routine influenza vaccination is recommended for all persons aged ≥6 months. This represents an expansion of the previous recommendations…and is supported by evidence that annual influenza vaccination is a safe and effective preventive health action with potential benefit in all age groups."[7]

"Vaccination to prevent influenza is particularly important for the following persons who are at increased risk for severe complications from influenza or at higher risk for influenza-related outpatient, ED, or hospital visits:…all persons aged ≥50 years;… adults and children who have chronic pulmonary (including asthma) or cardiovascular (except isolated hypertension), renal, hepatic… or metabolic disorders (including diabetes mellitus);…residents of nursing homes and other long-term–care facilities; [and] household contacts and caregivers of persons with medical conditions that put them at higher risk for severe complications from influenza."[7]

Live, Attenuated Influenza Vaccine (LAIV) **CONTRAINDICATED**

"Persons at higher risk for complications of influenza infection because of underlying medical conditions should not receive LAIV. Persons at higher risk for complications of influenza infection because of underlying medical conditions include adults and children with chronic disorders of the pulmonary or cardiovascular systems; adults and children with chronic metabolic diseases (including diabetes mellitus), renal dysfunction, hemoglobinopathies, or immunnosuppression… and residents of nursing homes and other chronic-care facilities that house persons with chronic medical conditions." [8]

Use of influenza antivirals for persons with impaired renal function[9]

Zanamivir. Limited data are available regarding the safety and efficacy of zanamivir for patients with impaired renal function. Among patients with renal failure who were administered a single intravenous dose of zanamivir, decreases in renal clearance, increases in half-life, and increased systemic exposure to zanamivir were reported. However, a limited number of healthy volunteers who were administered high doses of intravenous zanamivir tolerated systemic levels of zanamivir that were substantially higher than those resulting from administration of zanamivir by oral inhalation at the recommended dose. On the basis of these considerations, the manufacturer recommends no dose adjustment for inhaled zanamivir for a 5-day course of treatment for patients with either mild-to-moderate or severe impairment in renal function.

Oseltamivir. Serum concentrations of oseltamivir carboxylate (GS4071), the active metabolite of oseltamivir, increase with declining renal function. For patients with creatinine clearance of 10-30 mL/min, a reduction of the treatment dosage of oseltamivir to 75 mg once daily and in the chemoprophylaxis dosage to 75 mg every other day is recommended. Treatment or chemoprophylaxis dosing recommendations have been proposed for patients undergoing routine renal dialysis treatment but are based on limited pharmacokinetic data.

Pneumococcal Vaccine

23-Valent Pneumococcal Polysaccharide Vaccine (PPSV23)

The 23-valent pneumococcal polysaccharide vaccine (PPSV23; Pneumovax 23, Merck & Co. Inc.) contains 12 of the serotypes included in 13-valent pneumococcal conjugate vaccine (PCV13; Prevnar 13, Wyeth Pharmaceuticals, Inc., a subsidiary of Pfizer, Inc.), plus 11 additional serotypes. PPSV23 is recommended for prevention of invasive pneumococcal disease (IPD) among all adults aged ≥65 years, and for adults at high risk aged 19–64 years. Given the high burden of IPD caused by serotypes in PPSV23 but not in PCV13, broader protection might be provided through use of both pneumococcal vaccines.

The current ACIP PPSV23 recommendations call for vaccination of adults at high risk aged 19–64 years at the time of diagnosis of the high-risk condition. A one-time revaccination dose of PPSV23 is recommended 5 years after the first dose for persons with functional or anatomic asplenia and for immunocompromised persons. All adults are eligible for a dose of PPSV23 at age 65 years, regardless of previous PPSV23 vaccination; however, a minimum interval of 5 years between PPSV23 doses should be maintained. [10]

"Vaccination is . . . recommended for immunocompromised adults at increased risk of pneumococcal disease or its complications (e.g., persons with splenic dysfunction or anatomic asplenia, Hodgkin's disease, leukemia, lymphoma, multiple myeloma, chronic renal failure, nephrotic syndrome, or conditions such as organ transplantation associated with immunosuppression)." [1]

13-Valent Pneumococcal Conjugate Vaccine (PCV13)

On June 20, 2012, the Advisory Committee on Immunization Practices (ACIP) recommended routine use of 13-valent pneumococcal conjugate vaccine (PCV13)) for adults aged ≥19 years with immunocompromising conditions (including those with chronic renal failure or nephrotic syndrome), functional or anatomic asplenia, cerebrospinal fluid (CSF) leaks, or cochlear implants. PCV13 should be administered to eligible adults in addition to the 23-valent pneumococcal polysaccharide vaccine (PPSV23), the vaccine currently recommended for these groups of adults.[10]

The ACIP recommendation for routine vaccination with PCV13 and the immunization schedules for children aged ≤59 months who have not received any previous conjugate vaccine (PCV7) or PCV13 doses are the same as those published previously for PCV7, with PCV13 replacing PCV7 for all doses. For routine immunization of infants, PCV13 is recommended as a 4-dose series at ages 2, 4, 6, and 12--15 months. Infants and children who have received ≥1 dose of PCV7 should complete the immunization series with PCV13. A single supplemental dose of PCV13 is recommended for all children aged 14--59 months who have received 4 doses of PCV7 or another age-appropriate, complete PCV7 schedule. For children who have underlying medical conditions, a supplemental PCV13 dose is recommended through age 71 months.[11] A single dose of PCV13 may be administered for children aged 6-18 with high-risk conditions such as functional or anatomic asplenia, immunocompromising conditions, cochlear implants, or CSF leaks, regardless of whether they have previously received PCV7 or PPSV23.[10] Children aged 2--18 years with underlying medical conditions also should receive PPSV23 after completing all recommended doses of PCV13.[11]

Adults with specified immunocompromising conditions who are eligible for pneumococcal vaccine should be vaccinated with PCV13 during their next pneumococcal vaccination opportunity. ACIP recommends that adults aged ≥19 years with immunocompromising conditions, functional or anatomic asplenia, CSF leaks, or cochlear implants, and who have not previously received PCV13 or PPSV23, should receive a dose of PCV13 first, followed by a dose of PPSV23 at least 8 weeks later. Subsequent doses of PPSV23 should follow current PPSV23 recommendations for adults at high risk. Specifically, a second PPSV23 dose is recommended 5 years after the first PPSV23 dose for persons aged 19–64 years with functional or anatomic asplenia and for persons with immunocompromising conditions. Additionally, those who received PPSV23 before age 65 years for any indication should receive another dose of the vaccine at age 65 years, or later if at least 5 years have elapsed since their previous PPSV23 dose. For adults aged ≥19 years with immunocompromising conditions, functional or anatomic asplenia, CSF leaks, or cochlear implants, who previously have received ≥1 doses of PPSV23 should be given a PCV13 dose ≥1 year after the last PPSV23 dose was received. For those who require additional doses of PPSV23, the first such dose should be given no sooner than 8 weeks after PCV13 and at least 5 years after the most recent dose of PPSV23.[10]

Tables 1-3 describe the recommended pneumococcal immunization schedule for chronic kidney disease patients (Appendix).

References

1. **Recommendations of the Advisory Committee on Immunization Practices (ACIP): Use of Vaccines and Immune Globulins for Persons with Altered Immunocompetence.** ***MMWR Recommendations and Reports.*** **Apr 9 1993;42(RR-4):1-18.**
2. **National Center for Immunization Respiratory Diseases. General Recommendations on Immunization --- Recommendations of the Advisory Committee on Immunization Practices (ACIP).** ***MMWR Recommendations and Reports.*** **Jan 28 2011;60(2):1-64.**
3. **Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients.** ***MMWR Recommendations and Reports.*** **Apr 27 2001;50(RR-5):1-43.**
4. **Mast EE, Weinbaum CM, Fiore AE, et al. A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP) Part II: Immunization of Adults.** ***MMWR Recommendations and Reports.*** **Dec 8 2006;55(RR-16):1-33.**
5. **Mast EE, Margolis HS, Fiore AE, et al. A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP) Part 1: Immunization of Infants, Children, and Adolescents.** ***MMWR Recommendations and Reports.*** **Dec 23 2005;54(RR-16):1-31.**
6. **Centers for Disease Control and Prevention. Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP)--United States, 2012-13 Influenza Season.** ***MMWR Morbidty and Mortality Weekly Report.*** **Aug 17 2012;61(32):613-618.**
7. **Fiore AE, Uyeki TM, Broder K, et al. Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010.** ***MMWR Recommendations and Reports.*** **Aug 6 2010;59(RR-8):1-62.**
8. **Fiore AE, Shay DK, Broder K, et al. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009.** ***MMWR Recommendations and Reports.*** **Jul 31 2009;58(RR-8):1-52.**
9. **Fiore AE, Fry A, Shay D, Gubareva L, Bresee JS, Uyeki TM. Antiviral Agents for the Treatment and Chemoprophylaxis of Influenza --- Recommendations of the Advisory Committee on Immunization Practices (ACIP).** ***MMWR Recommendations and Reports.*** **Jan 21 2011;60(1):1-24.**
10. **Centers for Disease Control and Prevention. Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine for Adults with Immunocompromising Conditions: Recommendations of the Advisory Committee on Immunization Practices (ACIP).** ***MMWR Morbidty and Mortality Weekly Report.*** **Oct 12 2012;61:816-819.**
11. **Nuorti JP, Whitney CG. Prevention of Pneumococcal Disease Among Infants and Children - Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine - Recommendations of the Advisory Committee on Immunization Practices (ACIP).** ***MMWR Recommendations and Reports.*** **Dec 10 2010;59(RR-11):1-18.**
12. **Nuorti JP, Whitney CG. Updated Recommendations for Prevention of Invasive Pneumococcal Disease Among Adults Using the 23-Valent Pneumococcal Polysaccharide Vaccine (PPSV23).** ***MMWR Morbidty and Mortality Weekly Report.*** **Sep 3 2010;59(34):1102-1106.**

Appendix

Table 1. Guidelines for administering PCV13 and PPSV23 vaccines for infants and children (ages 0-18) with chronic kidney disease

Infants and Children (ages 0-18)				
Vaccination History	**Recommended Regimen**			**Notes**
Never vaccinated with PCV7 or PCV13 up to age 59 months	Routine vaccination for PCV13 (4 dose series)	Administer 1 dose of PPSV23 at age ≥2 years and ≥8 weeks after last indicated dose of PCV13	Administer 1 dose of PPSV23 5 years later	The ACIP recommendation for routine vaccination with PCV13 and the vaccination schedules for infants and toddlers through age 59 months who have not received any previous PCV7 or PCV13 doses are the same as those previously published for PCV7. PCV13 is recommended as a 4-dose series at ages 2, 4, 6, and 12–15 months.[11]
Completed all recommended doses of PCV7	Administer 1 dose of PCV13 ≥8 weeks later	Administer 1 dose of PPSV23 at age ≥2 years and ≥8 weeks after last indicated dose of PCV13	Administer 1 dose of PPSV23 5 years later	For children who have underlying medical conditions, a single supplemental PCV13 dose is recommended through 71 months of age. This includes children who have received PPSV23 previously. PCV13 should be administered at least 8 weeks after the most recent dose of PCV7 or PPSV23. This will constitute the final dose of PCV for these children.[11]
Children aged 24-71 months who received <3 doses of PCV7 before age 24 months	Administer 2 doses of PCV13 now	Administer 1 dose of PPSV23 ≥8 weeks later after last indicated dose of PCV13	Administer 1 dose of PPSV23 5 years later	Children aged 24–71 months with underlying medical conditions who received <3 doses of PCV7 before age 24 months should receive a series of 2 doses of PCV13 followed by 1 dose of PPSV23 administered ≥8 weeks later.[11]
Children aged 24-71 months who received any incomplete schedule of 3 doses of PCV7 before age 24 months	Administer 1 dose of PCV13 now	Administer 1 dose of PPSV23 ≥8 weeks later	Administer 1 dose of PPSV23 5 years later	Children aged 24–71 months with underlying medical conditions who received any incomplete schedule of 3 doses of PCV7 before age 24 months should receive 1 dose of PCV13 followed by 1 dose of PPSV23 administered ≥8 weeks later.[11]
Completed all recommended doses of PCV13	Administer 1 dose of PPSV23 at age ≥2 years and ≥8 weeks after last indicated dose of PCV13	Administer 1 dose of PPSV23 5 years later		A second dose of PPSV23 is recommended 5 years after the first dose of PPSV23 for children who have anatomic or functional asplenia, including SCD, HIV infection, or other immunocompromising condition.[11]
Children aged 6-18 years who have not received PCV13	Administer 1 dose of PCV13 now			One dose of PCV13 is recommended by ACIP for children aged 6-18 years with high-risk conditions such as functional or anatomic asplenia, immunocompromising conditions, cochlear implants, or CSF leaks.[10]

Table 2. Guidelines for administering PCV13 and PPSV23 vaccines for adults (ages 19-64) with chronic kidney disease

Adults (ages 19-64)				
Vaccination History	**Recommended Regimen**			**Notes**
Never vaccinated with PCV13 or PPSV23	Administer 1 dose of PCV13 dose now	Administer 1 dose of PPSV23 ≥ 8 weeks later	Administer 1 dose of PPSV23 ≥ 5 years later	ACIP recommends that adults aged ≥19 years with immunocompromising conditions, functional or anatomic asplenia, CSF leaks, or cochlear implants, and who have not previously received PCV13 or PPSV23, should receive a dose of PCV13 first, followed by a dose of PPSV23 at least 8 weeks later. Subsequent doses of PPSV23 should follow current PPSV23 recommendations for adults at high risk. Specifically, a second PPSV23 dose is recommended 5 years after the first PPSV23 dose for persons aged 19–64 years with functional or anatomic asplenia and for persons with immunocompromising conditions. Additionally, those who received PPSV23 before age 65 years for any indication should receive another dose of the vaccine at age 65 years, or later if at least 5 years have elapsed since their previous PPSV23 dose.[10]
Previously vaccinated with 1 dose PPSV23 ≥ 1 year ago; never vaccinated with PCV13	Administer 1 dose of PCV13 dose now	Administer 1 dose of PPSV23 ≥ 8 weeks after PCV13, which must be ≥ 5 years after first dose of PPSV23		
Previously vaccinated with 2 doses of PPSV23 (last dose was ≥ 1 year ago); never vaccinated with PCV13	Administer 1 dose of PCV13 dose now			
Previously vaccinated with ≥ 1 dose PCV13 (≥8 weeks ago); never vaccinated with PPSV23	Administer 1 dose of PPSV23 now	Administer 1 dose of PPSV23 ≥5 years later		
Previously vaccinated with ≥ 1 dose PCV13 (≥8 weeks ago) and 1 dose PPSV23	Administer 1 dose of PPSV23 ≥5 years after first PPSV23 dose			

Table 3. Guidelines for administering PCV13 and PPSV23 vaccines for adults (ages 65 and over) with chronic kidney disease

Adults (ages 65 and over)			
Vaccination History	**Recommended Regimen**		**Notes**
Never vaccinated with PCV13	Administer 1 dose of PCV13 now	Administer 1 dose of PPSV23 ≥ 8 weeks after PCV13, which must be ≥ 5 years after last dose of PPSV23	All persons should be vaccinated with PPSV23 at age 65 years. Those who received PPSV23 before age 65 years for any indication should receive another dose of the vaccine at age 65 years or later if at least 5 years have passed since their previous dose. Those who receive PPSV23 at or after age 65 years should receive only a single dose.[12]
Previously vaccinated with ≥ 1 dose PCV13 (≥8 weeks ago)	Administer 1 dose of PPSV23 now		